

SOUTHEASTERN FERTILITY CENTER, P.A.
INFERTILITY
REPRODUCTIVE ENDOCRINOLOGY



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December 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #97-N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To Whom It May Concern:

This letter is with respect to Docket #97-N-484S. This is my strong disagreement with this proposed ruling.

Quarantining embryos will significantly increase the cost and will increase the number of cycles needed to obtain the same pregnancies. It will also decrease the success rate for donor IVF. I think the FDA is interfering with the practice of medicine by attempting to require quarantining of embryos resulting from donor oocyte IVF. Quarantining will significantly increase costs and decrease success rates.

Sincerely yours,

Robert A. Kaufmann, M.D.

RAK/shb

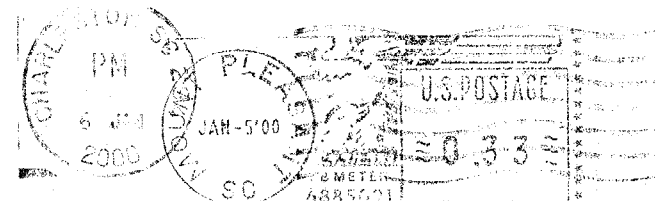
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